

Section 5: 510(k) Summary

5 510(k) Summary

OCT 3 1 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Date of summary preparation: August 24th, 2007

Manufacturer

Siemens AG, Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

Headquarters:

Siemens AG
Wittelsbacherplatz 2
D-80333 Munich, Germany

Registration Number 8010024

Importer/Distributor

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Contact Person

Mr. Lutz Mahn
Regulatory Affairs Manager
Henkestrasse 127
D-91052 Erlangen, Germany
Phone: +49 (9131) 84-2274
Fax: +49 (9131) 84-2200
e-mail: lutz.mahn@siemens.com

Section 5: 510(k) Summary

Classification and Device Name

Classification Panel: Radiology
 Classification Name: Magnetic Resonance Diagnostic Device Accessory
 Device Class: Class II [21 CFR § 892.1000]
 Product Code: MOS
 Common Name: Volume Coil
 Trade Name: 1.5 T 32-channel Head Coil
 3 T 32-channel Head Coil

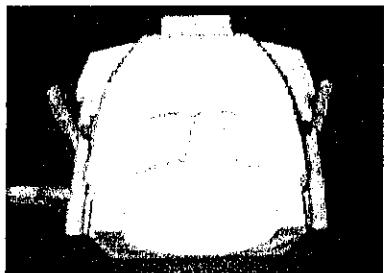
II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The 1.5T 32-channel Head Coil and the 3T 32-channel Head Coil are indicated for use as magnetic resonance diagnostic devices (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Device Description

The 1.5T 32-channel Head Coil and the 3T 32-channel Head Coil are receive only MR coils



for imaging the human head. The coils comprises a split design for easy patient positioning. An addition mirror is provided for patient comfort. A high number of 32 receive elements has been chosen to make use of high acceleration factors in the so-called parallel imaging technique (iPAT). The inner dimensions of the coil have been chosen to be smaller than the Head Matrix Coil to optimize the signal-to-noise ratio.

Substantial Equivalence

Siemens believes that the 1.5T 32-channel Head Coil and the 3T 32-channel Head Coil are substantially equivalent to the following cleared medical devices:

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
Siemens MAGNETOM Avanto 1.5T (Head MATRIX coil)	K032428	Oct 16, 2003
Siemens MAGNETOM Trio a Tim System 3T (Head MATRIX coil)	K050200	Feb 28, 2005

General Safety and Effectiveness Concerns:

Section 5: 510(k) Summary

The following safety and performance parameters:

[Safety]

- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]

- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

The following parameters were considered for the new **1.5T 32-channel Head Coil** and the **3T 32-channel Head Coil**

[Safety]

- Biocompatibility

[Performance]

- Signal to Noise Ratio
- Image Uniformity

No new materials were used for the new **1.5T 32-channel Head Coil** and the **3T 32-channel Head Coil** compared to their predicate device. Therefore no new biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests acc. to IEC 62464-1 standard were performed for the new **1.5T 32-channel Head Coil** and the **3T 32-channel Head Coil** and the results presented in this submission show that they are equivalent with the predicate devices.

Conclusion as to Substantial Equivalence

Laboratory testing was performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

Siemens AG Medical Solutions
c/o Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K072909

Trade/Device Name: 1.5T 32-channel Head Coil and 3T 32-channel Head Coil

Regulation Number: 21 CFR §892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: MOS

Dated: October 8, 2007

Received: October 12, 2007

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

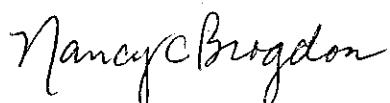
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market..

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section: 4: Indications for Use Statement

4 Indications for Use Statement

510(k) Number (if known) K072909

Device Name: 1.5T 32-channel Head Coil and 3T 32-channel Head Coil

Indications for Use:

The intended uses of the 1.5T 32-channel Head Coil and the 3T 32-channel Head Coil are, in conjunction with a Magnetic Resonance Scanner, the MR examination of the human head.

Used in the 1.5 T MAGNETOM Avanto, MAGNETOM Espree or MAGNETOM Symphony, a Tim System, the 1.5 T 32-channel Head Coil and in the 3 T MAGNETOM Trio, a Tim System, the 3T 32-channel Head Coil are indicated for uses as a diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the body. The images produced by the 1.5 T MAGNETOM Avanto, MAGNETOM Espree or MAGNETOM Symphony, a Tim System with the 1.5 T 32-channel Head Coil and the images produced by the 3 T MAGNETOM trio a Tim System with the 3T 32-channel Head Coil reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

The intended use of the MAGNETOM Avanto, MAGNETOM Espree or MAGNETOM Symphony a Tim System is not affected in any way by the use of the new 1.5T 32-channel Head Coil.

The intended use of the MAGNETOM Trio a Tim System is not affected in any way by the use of the new 3T 32-channel Head Coil.

(Please do not write below this line- continue on another page if needed)

Received

OCT 12 2007

FDA CDRH DMC

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X

OR

Over-The-Counter Use

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K072909